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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/038,894	03/11/1998	ROLAND STOUGHTON	UCSD-117	8909
39013 7590 02/16/2010 MOAZZAM & ASSOCIATES, LLC 7601 LEWINSVILLE ROAD SUITE 304 MCLEAN, VA 22102				
EXAMINER				
MELLER, MICHAEL V				
ART UNIT		PAPER NUMBER		
1655				
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**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

# Office Action Summary

## Application No.

09/038,894

## Applicant(s)

STOUGHTON ET AL.

## Examiner

Michael V. Meller

## Art Unit

1655

**-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --**  
**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 14 January 2010.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 10, 12, 13, 15-18, 32, 33, 35, 36, 38 and 41 is/are pending in the application.
- 4a) Of the above claim(s) 16, 17, 33, 36 and 38 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 10, 12, 13, 15, 18, 32, 35, 41 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

## Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SF-08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *Election/Restrictions*

The election of species of record is maintained for the reasons of record.

Applicant elected trauma as the disease/condition, futhan (nafamostate mesilate aka 6- amidino-2-naphthyl p-guanidinobenzoate dimethanesulfonate-see claims 18 and 41) as the protease inhibitor (activation lowering therapy) and free radical production as the cell activation assessment method. Thus, claims 16, 17, 33, 36, 38 are withdrawn from further consideration as being drawn to non-elected inventions.

Applicant argues that claims 17, 33 and 38 should not be withdrawn from consideration but it is clear that these claims were subjected to an election of species requirement as noted above. Since applicant elected trauma as the disease/condition, futhan (nafamostate mesilate) as the activation lowering therapy (protease inhibitor) and free radical production as the cell activation assessment method, claims 17, 33 and 38 are withdrawn since they claim non-elected subject matter since the disease/condition elected was trauma which is not in claim 17 and since futhan was elected as the activation lowering therapy then claims 33 and 38 are withdrawn from consideration

since they do not include futhan. Further, claims 16 and 36 are withdrawn since they are drawn to non-elected protease inhibitors.

Thus, claims 16, 17, 33, 36, 38 are withdrawn from further consideration by the examiner as being drawn to non-elected subject matter. This requirement has already been made FINAL.

***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 10, 12, 13, 15, 18, 32, 35, 41 are rejected under 35 U.S.C. 103 as being obvious over Rabkin et al. (US 5917013) in view of Groutas (US 5550139) and further in view of JP 409040579.

Rabkin teaches that free radical production associated with oxidative stress is measured using assays such as colormetric assays, see col. 9, lines 40-50. Thus, Rabkin teaches to assess the damage of a disease(s)/condition(s) such as inflammatory disorders such as tissue trauma (as evidenced by Groutas, since Groutas teaches that inflammation is associated with tissue trauma) by assessing the free radical production as taught by Radkin (column 9, lines 40-50). Note also that Rabkin teaches that his invention could be administered to someone who has inflammatory disorders, see column 2, lines 40-60. Thus, once inflammation was detected, then treatment would be administered which would mean that the inflammation was elevated which is why it was detected.

Rabkin does not teach to use a protease inhibitor such as futhan (nafamostat mesilate aka 6- amidino-2-naphthyl p-guanidinobenzoate dimethanesulfonate) as the treatment of the trauma once it is determined that treatment is needed for the trauma.

Groutas teaches that inflammation is associated with tissue trauma. Groutas also teaches that a serine protease such as alpha-1-proteinase inhibitor is administered to reduce inflammation, see column 1, lines 1-45. Thus, as with the teachings of Adams as

noted by the Board, the administration of alpha-1-proteinase will also treat the inflammation within the scope of the claims.

JP teaches that futhan (nafamostate mesilate aka 6- amidino-2-naphthyl p-guanidinobenzoate dimethanesulfonate) is well known to be used to treat inflammation, specifically inflammatory bowel disease, see abstract. It establishes that one of ordinary skill in the art would have known at the time the invention was made that futhan (nafamostate mesilate aka 6- amidino-2-naphthyl p-guanidinobenzoate dimethanesulfonate) was known to treat inflammation.

Thus, it would have been obvious to use a protease inhibitor such as the elected futhan (nafamostate mesilate aka 6- amidino-2-naphthyl p-guanidinobenzoate dimethanesulfonate) of Groutas and JP as the treatment in Rabkin when inflammation was detected since Groutas makes it clear that inflammation is associated with tissue trauma and thus it would be clearly obvious to treat trauma (as elected ) with a compound which is known to treat inflammation effectively, in fact JP teaches that futhan (nafamostate mesilate aka 6- amidino-2-naphthyl p-guanidinobenzoate dimethanesulfonate) is known to treat IBS (irritable bowel syndrome) effectively.

Claims 10, 12, 13, 15, 18, 32, 35, 41 are rejected under 35 U.S.C. 103 as being obvious over WO 92/15707 in view of Groutas (US 5550139) and further in view of JP 409040579.

WO teaches that free radical production is assayed by using immunoassay methods, see abstract, page 20, line 15-page 21, line 10. WO uses its compositions to treat (therapy) of inflammatory diseases, see abstract.

WO states that not only may this permit appropriate actions to avoid the pathogenic potential of these antibodies, but the detection serves in itself as a sensitive measure of ongoing oxidative damage. As noted in the abstract, the immunoassay methods are used to diagnose inflammatory diseases as well as monitoring of the progress or therapy of such diseases or conditions. Thus, once inflammation was detected, then treatment would be administered which would mean that the inflammation was elevated which is why it was detected.

WO does not teach to use a protease inhibitor such as futhan (nafamostat mesilate aka 6- amidino-2-naphthyl p-guanidinobenzoate dimethanesulfonate) as the treatment of the trauma once it is determined that treatment is needed for the trauma.

Groutas teaches that inflammation is associated with tissue trauma. Groutas also teaches that a serine protease such as alpha-1-proteinase inhibitor is administered to reduce inflammation, see column 1, lines 1-45. Thus, as with the teachings of Adams as

noted by the Board, the administration of alpha-1-proteinase will also treat the inflammation within the scope of the claims.

JP teaches that futhan (nafamostate mesilate aka 6- amidino-2-naphthyl p-guanidinobenzoate dimethanesulfonate) is well known to be used to treat inflammation, specifically inflammatory bowel disease, see abstract. It establishes that one of ordinary skill in the art would have known at the time the invention was made that futhan (nafamostate mesilate aka 6- amidino-2-naphthyl p-guanidinobenzoate dimethanesulfonate) was known to treat inflammation.

Thus, it would have been obvious to use a protease inhibitor such as the elected futhan (nafamostate mesilate aka 6- amidino-2-naphthyl p-guanidinobenzoate dimethanesulfonate) of Groutas and JP as the treatment in WO when inflammation was detected since Groutas makes it clear that inflammation is associated with tissue trauma and thus it would be clearly obvious to treat trauma (as elected ) with a compound which is known to treat inflammation effectively, in fact JP teaches that futhan (nafamostate mesilate aka 6- amidino-2-naphthyl p-guanidinobenzoate dimethanesulfonate) is known to treat IBS (irritable bowel syndrome) effectively.



Any inquiry concerning this communication or earlier communications from the examiner should be directed to Michael V. Meller whose telephone number is 571-272-0967. The examiner can normally be reached on Monday thru Thursday: 9:30am-6:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey can be reached on 571-272-0775. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael V. Meller/

Primary Examiner, Art Unit 1655

